

of congestion from discarded tissue * * * beneficial in healing slightly * * * inflamed tissues * * * If there is any soreness, due to discharge, inflammation or other causes, * * * Four Leaf Clovers will speedily alleviate this condition. * * * Leucorrhoea Approximately ninety per cent of women suffer from Leucorrhoea, commonly known as 'Whites', at some period in life. Directly or indirectly, it is a contributing cause to practically every disease of women. Four Leaf Clovers, because of their positive antiseptic qualities, quickly aid nature in correcting this condition. * * * Menopause. By many the Menopause, or Change of Life, is considered the most dangerous period of a woman's life. One can alleviate the suffering and help reduce the amount of what is commonly called 'hot flashes' by inserting one Four Leaf Clover into the vaginal tract upon retiring, * * * The treatment is simple, reduces the irritation of the area, and is very beneficial. 'I have been suffering from Leucorrhoea for several years and have tried everything I could find for relief. A 30-day treatment with Four Leaf Clovers has made a new woman out of me. I am no longer nervous and I have regained my strength.'

On June 1, 1936, the Pilgrim Co., having consented to a decree, judgment of condemnation was entered and it was ordered that the product be destroyed.

M. L. WILSON,

Acting Secretary of Agriculture.

26500. Misbranding of Mentos. U. S. v. 262 Bottles of Mentos. Default decree of condemnation and destruction. (F. & D. no. 87538. Sample no. 67574-B.)

This case involved an interstate shipment of Mentos the bottles of which and an accompanying circular, bore and contained false and fraudulent representations regarding its curative or therapeutic effect.

On April 4, 1936, the United States attorney for the District of New Jersey, acting upon a report by the Secretary of Agriculture, filed in the district court a libel praying seizure and condemnation of 262 bottles of Mentos at Atlantic City, N. J., alleging that the article had been shipped in interstate commerce on or about January 29, 1936, from Philadelphia, Pa., by Mentos Products, Inc., and that it was misbranded in violation of the Food and Drugs Act as amended.

Analysis of the article showed that it consisted essentially of sulphur, borax, ammonia, and water, with small quantities of perfume materials.

The article was alleged to be misbranded in that statements borne on the bottle labels and contained in an accompanying circular, regarding the curative or therapeutic effects of the article, falsely and fraudulently represented that the article was capable of promoting new growth of hair; was capable of stopping dandruff, falling hair, scaling scalp, eczema, ringworm, and sores; was capable of curing all scalp disorders, such as psoriasis, eczema, severe cases of dandruff, falling hair, and scaling scalp, by penetrating the hair follicles, stimulating the glands, and causing the blood to circulate freely and nourish the roots of the hair; would be effective in the treatment of baldness and loss of hair; would cure the worst cases of dandruff, eczema, and sores; would stop and prevent hair from falling out by killing germs, curing germ diseases, and medicating the glands; was capable of stopping and curing falling hair, however severe the case, and of producing a luxuriant growth of hair; would prevent and cure baldness; would keep the scalp clean of dandruff and awaken dead tissues and the roots of the hair; would restore the hair and aid in curing skin diseases; would cure and prevent dandruff, restore hair, and cure any kind of skin disease of the head, face, and body, and any kind of infection of the scalp or skin, skin eruptions, and warts.

On June 6, 1936, no claimant having appeared, judgment of condemnation was entered and it was ordered that the product be destroyed.

M. L. WILSON,

Acting Secretary of Agriculture.

26501. Alleged misbranding of Diaplex. U. S. v. Horace Wayne Pierce and William Jess Predmore. Tried to a jury. Verdict of not guilty. (F. & D. no. 35984. Sample nos. 15449-B, 26527-B, 26528-B.)

This case involved interstate shipments of Diaplex the packages of which bore allegedly false and fraudulent statements regarding the curative or therapeutic effect of the article with respect to diabetes.

On April 29, 1936, the grand jurors of the United States in and for the District of Colorado returned in the district court an indictment against Horace Wayne Pierce and William Jess Predmore, Denver, Colo., charging shipment by said

defendants in violation of the Food and Drugs Act, as amended, on or about January 25, 1935, from the State of Colorado into the State of California, and on or about March 8 and March 25, 1935, from the State of Colorado into the State of Idaho, of quantities of Diaplex which was misbranded.

Analysis of the article showed that it consisted of coarsely ground stem material essentially identical with saltbush (*Atriplex*), occurring in arid and semiarid sections of western United States.

The article in the shipment of January 25, 1935, was alleged to be misbranded in that the following statements regarding the curative or therapeutic effect of the article, borne on the label, "Directions to Doctors. For those whose blood-sugar tests 125 mm. per cc. or over, use four heaping tablespoons of Diaplex to the quart of water and percolate ten to fifteen minutes. * * * Should the urine analysis show an increase of sugar, make blood test to determine cause. * * * Persons using Diaplex with insulin should make a urine test daily, and as the pancreas increases its normal function, reduce the amount of insulin sufficiently to avoid insulin reaction. Only use enough insulin to take care of the surplus sugar, but continue the use of Diaplex until you are well and strong", falsely and fraudulently represented that the article was effective as a treatment, remedy, and cure for diabetes.

The article in the shipments of March 8 and March 25, 1935, was alleged to be misbranded in that the following statements regarding the curative and therapeutic effect of the article, borne on the label, falsely and fraudulently represented that the article was effective as a treatment, remedy, and cure for diabetes: "Diaplex for diabetes Directions Use two to three heaping tablespoons full of Diaplex to each pint of water, then bring to a boil or percolate in a porcelain or earthen coffee percolator for ten minutes. (Never use aluminum utensils). Always serve Diaplex fresh and hot (never lukewarm or cold). A diabetic should drink at least two quarts of Diaplex daily, for from three to nine months. Also watch the urine test daily and you will be amazed at the results. Diaplex contains no opiates and is non-injurious. Persons using Diaplex with insulin should make the urine test daily, and as the pancreas increases its normal function, reduce the amount of insulin sufficiently to avoid insulin reaction. Only use enough insulin to take care of the surplus sugar, and eventually eliminate the insulin entirely. But continue the use of Diaplex until you are well and strong. Persons who have never used insulin, and not in coma, will find it unnecessary to do so. All that will be required is to adhere to a good diabetic diet and drink two quarts daily of Diaplex for a few months, and like thousands of others he too, will rejoice in the grand activity of good health and vigor. If we help you—you, too, may help others. If your druggist or health store doesn't handle it, write the Home Office and for further information address 'Diaplex', Postoffice Box 42, Denver, Colo., U. S. A."

On June 5, 1936, the case having come on for trial before a jury, the court delivered the following charge to the jury:

Strong, *District Judge*: Gentlemen of the jury: There are three counts in this indictment and each of the counts states a separate offense. You are to find a verdict of guilty or not guilty on each count.

The law which the defendant is charged with violating, briefly is known as the Pure Food and Drug Act, enacted by the Congress of the United States, and this makes it unlawful for anyone to ship in interstate commerce any article of food or drug which is misbranded within the meaning of this Statute. The law further says that an article is misbranded—that is to say, a drug is misbranded, if the package or the label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such articles, or any of the ingredients or substances contained therein which are false and fraudulent.

In this case it is admitted that the defendant, Mr. Pierce, made this preparation Diaplex, and it is admitted that he shipped it in interstate commerce as charged by the Government. The only question remaining for your consideration is whether the language on those packages which he shipped which had reference to the curative and therapeutic effect of the article was false and fraudulent. This is the sole question. The aim of this law is to prevent * * * as well as to prevent statements which are literally false. This is so that people may know by reading a label what they are getting and may rely thereon. In this connection it is up to the manufacturer to choose statements which will not deceive or mislead, and if you find that the labels used

by the defendant were liable to mislead the public—the public who would buy them—that they are fraudulent—then he is guilty of misbranding.

The testimony of the Government is that this preparation is made from a bush known as salt bush and that a tea or infusion prepared from it, in the manner directed, would contain (stated the chemical analysis of the product), and if you further believe from all the testimony of the case, including experts and others, that such a preparation would not be capable of exerting any beneficial therapeutic effects in the treatment of diabetes, then the labels are false.

You are further instructed, gentlemen, that the sole question in this case is not whether this preparation would cure diabetes, help it or would not, but it is a question also of the intent and good faith or lack of good faith of this defendant in putting this preparation on the market and shipping it in interstate commerce. You are not necessarily bound by the opinion of the medical profession as to the therapeutic value or lack of it. Medicine is a progressive science and what leading doctors today may use as a sure cure, they may discard tomorrow for something better, and it may be the doctors don't always take up a new discovery or recognize therapeutic value, if it has any, and their evidence is for the purpose of helping you to decide the case. In the final analysis, you gentleman must decide it and not the doctors or any of the others.

The defendant in dealing with a medical preparation and in putting it on the market, is charged with some superior knowledge as to the effects of the device or preparation that he puts out. A man who deals and holds himself out as this man did, with a cure for diabetes must know something about it. The purpose of the law is to prevent ignorant, dishonest, and unqualified people from selling medicines or preparations that might injure people or which have no value at all. So judging by that standard, as well as some others that I will give you, the testimony is made up of two classes: First, the doctors—men skilled in the art—and their testimony as to the nature of diabetes, its symptoms, the progress of the disease, and the treatment which the medical profession generally prescribe for it—among those restricted diet, use of insulin, and exercise. You also have the testimony of the Government of one or two people who used the preparation and derived no benefit—that some were even harmed by the use of it. The defendant also paraded before you gentlemen a good many people—no doubt honest in their belief—who stated they had used the remedy and derived great benefit. The evidence of lay witnesses should be considered by you with extreme caution. We know from our everyday experience that people like to talk about the diseases they have and have fixed opinions as to whether the remedy helped them or not. [Portion not repeated verbatim but it was to the effect that people with no superior medical knowledge were unable to make a definite statement as to whether or not a remedy helped them—that what they said could only be their opinion.] So you should scrutinize that evidence rather carefully, taking all points into consideration before giving it any weight. But if, after considering it, you feel it has some value, you should give it such weight as you feel it is entitled to.

It is not necessary that the statements that the defendant makes are directly false. You are entitled to take the language on the label or as set forth in the indictment, and ask yourself: "How would that strike the average intelligent person who would buy it? Does it directly or indirectly say that it will cure diabetes if used in the manner prescribed?" What is the effect of the language used? Did he convey the impression that it is a cure or remedy for the disease? He must have knowledge that it was false, or he must have made the label statements recklessly and with total disregard of whether they were true or not, and without a firm and honest belief in the truth of it, and he cannot shut his eyes to obvious facts which he should have known. He didn't look it up. Made no investigation or study. Believed it to be all right. He has to assume some responsibility when he puts out a remedy to the public for a serious disease like diabetes. So in the final analysis, gentlemen, the thing is to analyze the evidence and decide whether a reasonable and prudent man, careful of the lives of others, conscious of the fact that medicine is * * * whether a reasonable and honest man would have put this out and can sincerely believe that it was what he represented and thought it to be. Now that is the test in the case.

On the one extreme, he is not bound by any guaranty. That is, he doesn't have to guarantee that it will cure. On the other hand, he has to be honest, sincere, and must have taken precautions which a man should take in selling

a product of this kind. Now he says that he relied upon letters he received from people who used the product. Ask yourself whether, as a reasonable and prudent man, he should have relied upon them. Did these people who made the statement know what they were talking about? For instance, he would not be justified in getting letters from a lot of ignorant people and coming into Court and saying that was his defense. On the other hand, if he had a right to believe that these people were sincere in their statements they made to him you might find * * * had a right to rely to some extent on their opinion.

Also, there is evidence * * * to find out what the effect of this remedy was. He shipped 100 packages to one doctor and asked him to test it out. He says he read up a little on diabetes—read one or two books. There is no evidence he ever attended a medical school or practiced medicine, or that he was educated sufficiently to hold himself out as one qualified to treat diseases—entirely lacking in that respect.

After reviewing the evidence, if you have a reasonable doubt as to any material fact necessary to constitute grave doubt, then he is entitled to the benefit of that doubt. * * * that the statement contained on the label was false and misleading. Also that the man was with fraud in making those representations or was so reckless and had such disregard as not to care whether it was a good remedy or not. [Here the judge described to the jury the definition of "Reasonable doubt".] You are the judges of the facts. You should not be influenced by anything I tell you. You are likewise judges of the credibility of the witnesses. It is up to you. You have the right to consider their manners on the witness stand as they gave their testimony. Do you think they were * * * interested in the outcome of the case? Qualified to testify?

Take the case, gentlemen, and consider it fairly and dispassionately and decide whether this man is guilty or not. There is no evidence that this remedy hurt anybody or might hurt anybody. That makes no difference because the law says he is guilty if he made statements which are untrue. People parted with their money in buying a worthless remedy. You have got to decide the case and consider all the surrounding circumstances and what you have heard on the witness stand. The question of intent is an illusive thing, but you are entitled to judge it as we judge each other in ordinary affairs of every day life, and if I do an act that brings about a certain result and you can say that it was bound to bring that result about, you can say I had that intent. Decide whether there was intent or lack of intent to violate this law. The arguments of the lawyers should not be considered. Decide what the facts are. Then it is your duty to take the instructions I have given you regarding the law and bring in your verdict accordingly. Do your best as far as it is humanly possible. * * *

If the defendant had an honest and sincere belief in the efficacy of this remedy you cannot find him guilty, but in judging whether he had that faith or not you should review the facts and determine whether he had total disregard and lack of care or interest in whether this remedy would cure * * * and if you find in the affirmative, the intent was fraud.

The jury retired and after due deliberation returned a verdict of not guilty for both defendants.

M. L. WILSON,
Acting Secretary of Agriculture.

26502. Adulteration of tincture of aconite. U. S. v. Mutual Pharmacal Co. Plea of guilty. Fine, \$25. (F. & D. no. 32137. Sample no. 41914-A.)

This case involved an interstate shipment of an article, labeled Tincture Aconite U. S. P., which differed from the standard of strength, quality, and purity prescribed for tincture of aconite in the United States Pharmacopoeia, and the standard of strength, quality, and purity of the article was not declared on the container thereof.

On May 13, 1935, the United States attorney for the Northern District of New York, acting upon a report by the Secretary of Agriculture, filed in the district court an information against the Mutual Pharmacal Co., a corporation, Syracuse, N. Y., charging shipment by said corporation in violation of the Food and Drugs Act, on or about June 11, 1933, from the State of New York into the State of Pennsylvania of an article, labeled "Tincture of Aconite U. S. P.", which was adulterated.